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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,411	02/14/2007	Andrew Bushell	ISI-101	1086

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,411	BUSHELL ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *60-84* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 12/19/2005, has been entered.
Claims 1-59 have been canceled.
Claims 60-84 have been added.

Claims 60-84 are pending and currently under Restriction Requirement set forth herein.

REQUIREMENT FOR UNITY OF INVENTION

2. As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:
As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use Of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 60-83, drawn to methods of treatment with antibodies and a non-cellular protein antigen.

Group II, claim 84, drawn regulatory T lymphocytes.

4. The inventions listed as Groups s I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-II lack unity of invention because even though the inventions of these groups require the technical feature of, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Padova et al. (U.S. Patent No. 7,169,389) (see entire document) in view of Barrat et al. (U.S. Patent No. 7,122,340) AND/OR Lazarus et al. (US 2004/0047862).

The technical feature shared by Groups I-II is regulatory T cells and the induction of regulatory T cells

Padova et al. teach methods of treating various conditions, including autoimmunity, with antibodies specific for CD154, CD4, CD8, LFA-1, CD80 and CD86 and CD58 (ICAM-1) as well as combination (see entire document, including pages 9-13).

Barret et al. teach methods of administering regulatory T cells for immunosuppression of inflammatory conditions, including autoimmunity (see Uses on columns 8-13), including the use of an exogenous antigen such as ovalbumin (e.g., see column 2, paragraph 2) (see entire document, including Summary of the Invention and Detailed Description of the Invention.
Also, Barret et al. teach that the regulatory T cells are $CD4^+$,$CD62L^+$ (e.g., see Regulatory T Cell Differentiation on columns 7-8).

Given the induction of regulatory T cells for immunosuppression of inflammatory conditions, including autoimmunity, the ordinary artisan artisan would have been motivated to combine human gamma globulin with other known therapeutic agents, such as those taught by Padova et al. in the inhibition of autoantibody responses in autoimmune patients, as well as to generate immunoregulatory T cell responses to inhibit deleterious immune responses in said autoimmune patients.

Lazarus et al. teach that human gamma globulin has been shown to induce immune tolerance or antigen-specific non-responsiveness in both B cells and T cells including the inhibition of autoantibody responses and enhanced suppressor T cell responses, (e.g., see paragraph [0014]).

Given the ability of IVIG and human gamma globulin to inhibit autoantibody responses and association with enhanced suppressor cell responses as taught by Lazarus et al., see entire document, including paragraph [0014]), the ordinary artisan would have been motivated to combine human gamma globulin with other known therapeutic agents, such as those taught by Padova et al. in the inhibition of autoantibody responses in autoimmune patients, as well as to generate immunoregulatory T cell responses to inhibit deleterious immune responses in said autoimmune patients.

Therefore, the shared technical feature of either inducing regulatory T cells or the regulatory T cells themselves of the present application does not make a contribution over the prior art.

Species Election

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
See Padova et al. (U.S. Patent No. 7,169,389) (see entire document) in view of Barrat et al. (U.S. Patent No. 7,122,340) AND/OR Lazarus et al. (US 2004/0047862) mentioned above.

The species are as follows:

6. If Group I is elected, applicant is required to elect a specific condition mediated by an immune response as recited in claims 63 or as describe on page 10, paragraph 2 or page 15, paragraph 1 of the instant specification *(e.g., rheumatoid arthritis, multiple sclerosis*).

7. In addition, if Group I or Group II (given the product-by-process limitation) is elected, applicant is required to elect a specific antibody specificity as recited in claim 60 *(e.g., anti-CD4 antibody, anti-CD8 antibody)*.

8. In addition, if Group I or Group II (given the product-by-process limitation) is elected, applicant is required to elect a specific non-cellular protein antigen as recited in claim 75 *(e.g., human gamma globulin, equine gamma globulin, ovalbumin)*.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

See Padova et al. (U.S. Patent No. 7,169,389) (see entire document) in view of Barrat et al. (U.S. Patent No. 7,122,340) AND/OR Lazarus et al. (US 2004/0047862) mentioned above.

9. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
Primary Examiner
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